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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,470	03/11/2004	Daniel H. Teitelbaum	UM-08764	7421

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,470	TEITELBAUM ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Co-operation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

Claims 1-17 are presented and represent all of the claims under consideration.

The use of the trademarks in claims 7 and 15 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants are requested to show the structure and provide other names for the compounds Bioproject BP1.137, Chiesi CHF 1514, Fisons FPL-66564, Marion Merrell Dow MDL-100240 and Servier S-5590 as recited in claims 7 and 15.

Claims 8-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the prevention of any symptom of inflammatory bowel disease. The specification provides no support for preventing a subject from experiencing symptoms of inflammatory bowel disease.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue

experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention of any symptom of inflammatory bowel disease.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the areas of gastroenterology.

Each particular inflammatory bowel disease has its own specific characteristics and etiology. The broad recitation "to prevent said subject from experiencing symptoms of inflammatory bowel disease" is inclusive of many conditions that presently have no established successful therapies. A successful treatment modality does not presage

success in preventing a subject at risk for inflammatory bowel disease from experiencing symptoms.

The breadth of the claims

Claim 8 is very broad and inclusive of any symptom of inflammatory bowel disease.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are directed to the administration of the angiotensin converting enzyme inhibitor enalaprilat to decrease apoptosis in a laboratory model for short bowel syndrome and for treating colitis. Results in mice studies are shown in Table 4, page 20.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound would be preferred for preventing the various symptoms of inflammatory bowel disease or short bowel syndrome that are encompassed in the claim language. The skilled artisan would expect the interaction of a particular compound in the prevention of a particular symptom of an inflammatory bowel disease to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among the various inflammatory bowel diseases to prevent a subject from experiencing symptoms. Absent reasonable *a priori* expectations of success for using a particular drug to prevent any particular symptom,

one skilled in the gastroenterology art would have to test extensively many compounds to discover which particular symptom responds to a particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Rodgers et al., U.s. Patent 6,821,953.

Rodgers teaches the administration of angiotensin converting enzyme (ACE) inhibitors in various inflammatory conditions of the bowel. Ulcerative colitis is an example of an inflammatory bowel disease. (Line 62, column 9) See column 3, lines 4-25, as well as lines 46-49. The open language of the present claims allows for the inclusion of any number of additional active agent in the claimed methods. See claim 11, column 34, where, as required by instant claims 16 and 17, an additional compound, besides an ACE inhibitor, capable of reducing a symptom of inflammatory bowel disease, is disclosed. See the paragraph bridging columns 9-10 where various modes of administration are disclosed. Rodgers' teaching encompasses all patient populations. Instructions, as part of a therapeutic preparation, are conventional.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Acton et al., U.S. Patent 6,632,830.

Acton teaches the administration of an angiotensin converting enzyme (ACE) inhibitor in the treatment of an inflammatory bowel disease. See column 36, lines 60-61, as well as lines17-34, where combination therapy with another therapeutic agent is disclosed. Modes of administration are disclosed in columns 41-43.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studdy et al., Lancet (abstract), particularly in view of Rao et al., Indian Journal of Pharmacology (abstract).

Studdy teaches the elevation of serum angiotensin-converting enzyme activity in patients with inflammatory bowel disease. Based on the abstract alone, it appears the inflammatory bowel disease, enteritis, is exemplified. Further, based on the abstract alone, the administration of angiotensin-converting enzyme inhibitors is suggested as a treatment. Motivation is provided to administer an angiotensin-converting enzyme inhibitor based on the teachings of Rao wherein the administration of the angiotensin-converting enzyme inhibitor, captopril, proved to be effective in causing a significant

reduction in ulcer index, an inflammatory characterization of stomach ulcer. (Entire copies of the articles will be supplied by FAX when they become available.)

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

December 26, 2005

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER